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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/368,572	08/05/1999	TOSHIHARU OHBA	OHBA=1A	5695

1444 7590 06/28/2002

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/28/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/368,572

Applicant(s)

OHBA ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) (Paper NO. 12) filed on May 14, 2002. The request for RCE is accepted and is established with the status of the application as follows:

- a. the filling date of this RCE is established as 8/08/99;
- b. Claims 3-6 are pending. Claims 1-2 and 7-12 are canceled.

2. Applicants' response to the earlier office action (Paper No. 10) filed on April 10, 2002 has been entered.

Response to Arguments

- 3. Applicant's response to the office action (Paper No.10) is fully considered and found not persuasive.
- 4. With respect to the rejection made in the previous office action under 35 U.S.C. 112 first paragraph, Applicant's arguments and amendment to claims 3-6 have been considered and the rejection is withdrawn herein.

New issues

Claim Rejections - 35 USC § 112

- 5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the Claimed invention.

The current claims are drawn to a genus of hybridizable fragments of SEQ ID Nos. 1-8. Specification describes in general hybridization conditions under which the hybridizable sequences of SEQ ID Nos. 1-8 could be screened, but no written description is provided with regards to all the possible hybridizable fragments comprising the sequences of SEQ ID Nos. 1-8. The large genus of fragments is represented in the specification by the named SEQ ID Nos. 1-8. Thus, applicant has expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a `representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common elements or attributes of the hybridizable sequences are disclosed with SEQ ID Nos. 1-8. With regard to hybridization conditions to obtain sequences hybridizable to SEQ ID Nos. 1-8, this is insufficient to demonstrate identity of any biological function where no structural information regarding where in the hybridizable fragment the promoter activity resides. Claims 3-6 are overly broad in the recitation of "a nucleotide sequence hybridizable to any one of SEQ ID Nos. 1-8 under hybridization conditions...", since no guidance is provided as to which of the myriad of hybridizable fragments encompassed by the claims will retain the promoter activity. Further no information is given in the specification regarding a methodology to determine such common elements or attributes.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until

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reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the sequence of the disclosed sequence numbers 1-8 are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description, which would demonstrate conception or written description of specific hybridizable fragments with the said limitations and retaining correlative function in the claimed sequences.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Okazawa et al.

(J Biol Chem., Vol. 268(34): 25364-25368).

Okazawa et al. teach screening of transformed or cloned plant promoter (endoxylglucan transferase), wherein Okazawa et al. disclose sequences hybridizable to the instant SEQ ID Nos. 1 and 2, under conditions of hybridization at 65⁰ C in a solution containing 6 x SSC, 0.1% SDS, 0.1 mg/ml salmon sperm DNA and 5% denhardt's solution (see sequence alignment from

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Gencore version 4.5, and page 25365, column 1, paragraph 3, column 2, Fig 1). The instant claims recite nucleotide sequence hybridizable to SEQ ID Nos. 1 and 2 and the calculated T_m for the sequence disclosed by Okazawa et al. is 75°C (see attached oligonucleotide T_m calculations). Thus any nucleotide fragment comprising said sequence hybridizes at 65°C under said hybridization conditions. Thus the disclosure of Okazawa et al. meets the limitations (hybridizable sequences) in the instant claims.

No claims are allowable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru

June 25, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER